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10/520,387

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Rita Boge Andersen

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EXAMINER

DEES, NIKKI H

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1781

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/520,387 | Applicant(s) ANDERSEN ET AL. | |
| | Examiner Nikki H. Dees | Art Unit 1781 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed June 19, 2008, has been entered. Claims 1-20 and 23-34 are currently pending in the Application. The previous objections to claims 2, 3, 5, 8-10, 15, 20, 24, and 32 have been withdrawn in view of the amendments to claims 2, 3, 5, 8-10, 15, 20, 24, and 32. The previous 112 rejections of claims 1 and 25-33 have been withdrawn in view of the amendments to claims 1 and 25-33. The previous rejections over Cherukuri have been withdrawn in view of Applicant's arguments.

Claim Objections

2. Claims 23 and 31 are objected to because of the following informalities:

Claim 23 line 7 change "ne" to "one";

Claim 31: change the first "aid" in line 2 to "said".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1, 2, 15, 20, 23, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 claims a first part of gum base granules and a second part of gum base granules comprising "conventional" gum base. It is unclear what differentiates the "conventional" gum base granules of the second part from the gum base granules of the first part. It is understood that the granules of the second part need not comprise flavor or active ingredients, but it is unclear what other differences the "conventional" description is intended to encompass.

6. Claim 2 claims a "flavor resistant resin". It is unclear what properties a resin must have to be "flavor resistant." Applicant's specification contains no direction as to what resins are, or are not, encompassed by this limitation.

7. Claim 15 claims a gum tablet having "an improved and sticky texture." It is unclear what textures meet the limitations of "improved and sticky."

8. Claim 20 claims sweetener in an amount by weight of the chewing gum. It is unclear if this is the weight of the chewing gum tablet or the chewing gum center.

9. Claim 23 claims a first and second gum base, where the first gum base is granulated. The first and second gum base are also blended. It is unclear if both gum bases are to be granulated, or if the first, granulated, gum base is to be incorporated into a second, non-granular, gum base.

10. Claim 25 claims a “conventional” gum base. As with claim 1, it is unclear how the conventional gum base is different from the gum base comprising the flavor and/or active ingredients.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6, 8-11, 14, 15, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang (EP 0 221 850).

13. Regarding claims 1-4, 8-11, and 15, Yang teaches compressed chewing gum tablets composed of granules including synthetic elastomer gum base, e.g. polyvinylacetate, or natural elastomer gum base (i.e. natural resin) (col. 8 line 47-col. 9 lines 14). Yang teaches a tablet may be made by blending two or more granulations before compressing, wherein at least one contains a flavorant (col. 11 lines 49-65). Though Yang does not speak to tackiness moderation, the presence of the natural resin meets the limitations of claims 9, 11 and 15 and it is considered inherent that it would affect the tackiness moderation as claimed.

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14. Regarding claim 5 the presence of any of wax (col. 9 lines 14-21), compression aid, lubricant, anti-adherent and glidant is optional, and thus, may or may not be present.

15. Regarding claim 6, Yang teaches the water content in their tablet of 2-5% (col. 2 lines 24-26).

16. Regarding claim 14, Yang teaches flavors in the composition at about 1 to 10% by weight (col. 10 lines 30-34).

17. Regarding claim 20, Yang teaches sweeteners in the tablet in an amount preferably from 60-98% bulk sweetener, with additional amounts of high-intensity sweetener (col. 9 lines 32-65). As this range significantly overlaps Applicant's claimed range, it is considered to anticipate the claim.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 7, 12, 13, 16-19, and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (EP 0 221 850).

20. Regarding claim 7, Yang teaches compression compounds over a range of 0.1% to 5%, and states that the range will vary broadly (col. 10 lines 21-23). One of ordinary

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skill would have found it obvious to provide a gum center substantially free of compression compounds if it was not desired to use a large amount of the compounds. Yang teaches that a smaller particle size increases the efficiency of the compression compounds. One of ordinary skill, through no more than routine experimentation, would have been able to determine the minimum amount of compression aid to use.

21. Regarding claims 12 and 13, Yang teaches natural resins and elastomers for use in the gum base (col. 8 line 47-col. 9 line 13). As it is well known to vary elastomers and natural resins in chewing gum compositions, one of ordinary skill would have been able to arrive at the desired texture through no more than routine experimentation with the amounts of natural resins and elastomers.

22. Regarding claims 16-19 and 34, Yang teaches and the optimum amount of each component in the gum tablet may or may not be present, and would require nothing more than routine experimentation by one reasonably skilled in this art (col. 9 lines 14-26). Further, it would have been obvious to use the magnesium stearate as a lubricant in the outer layer of the tablets since the purpose of the magnesium stearate is to reduce friction between the inner die wall and the tablet edge during ejection and to prevent capping (col. 10, lines 3-8)

23. Regarding claims 25-33, as the granules of Yang may comprise the natural and/or synthetic resins as detailed above, and at least two different granulates are combined in the compressed chewing gum tablet, the combination of two different granules comprising different elastomers, resins, flavors, etc. is considered to be obvious over the teachings of Yang.

24. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Athanikar et al. (6,322,828).

25. Athanikar et al. teach a method where a flavor is incorporated into a gum base (col. 4 lines 14-21). The gum base is then granulated in the presence of sweeteners and active ingredients (col. 3 lines 20-26; claim 1). The granulated composition is compressed into tablets (col. 7 lines 40-44).

26. Regarding the mixing of an elastomer and elastomer plasticizer to form a gum base, one of ordinary skill would have recognized that the synthetic elastomers of Athanikar et al. taught to be used in the gum base (col. 4 lines 21-25) are most commonly provided in combination with an elastomer plasticizer, and would have found it obvious to do so.

27. Athanikar et al. do not specifically refer to their sweeteners as bulk sweeteners. However, one of ordinary skill would have recognized that bulk sweeteners are commonly used in chewing gum products and would have found it obvious to utilize a bulk sweetener where the prior art teaches sweetener.

28. Athanikar et al. are silent as to the blending of a first and second gum base during the addition of further additives.

29. One of ordinary skill would have found it obvious to blend a first granulated gum base as taught by Athanikar et al. with a second granulated gum base as taught by Athanikar et al. to provide a tableted chewing gum comprising two different active ingredients. The blending of the first and second chewing gum bases is considered to

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be a duplication of parts and would have been expected to provide the predictable result of a chewing gum comprising two different active ingredients.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 1-20 and 25-34 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 8-12, 14-19, and 32 in copending Application No. 10/520,173. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to select any additives, including sweeteners and flavors, to be included in the gum center of the claims in 10/520,173 and for the barrier

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layer in the claims of 10/520,173 to fully encapsulate the gum center simply depending upon desired results, personal appeal and consumer preference.

32. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

33. Claims 1-20 and 25-34 are further provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 in copending Application No. 11/028,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to include sweeteners and flavors in the gum granules and compressed gum tablets in the claims of 11/028,684 since it is well known to prepare chewing gum products which include sweeteners and flavors.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

34. Claims 23 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-31 of copending Application No. 10/520,173 in view of Athanikar et al. (6,322,828) and Yang . Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to prepare two groups of gum granules as taught by Athanikar and then blend the two groups and compress them in the

claimed method of 10/520,173 since it is well known to prepare a chewing gum tablet by such a technique.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

35. Applicant's arguments filed June 19, 2008, have been fully considered but they are not persuasive with regard to the rejections over Yang.

36. Applicant argues that Yang does not teach a tablet having a center comprising chewing gum granules and additives (Remarks, p. 8).

37. The Examiner notes that Applicant appears to be arguing limitations that do not appear in the instant claims. There is no requirement that the tablet of the instant claims be coated. The compressed chewing gum tablet of Yang comprises two different chewing gum granules, as required by the instant claims. Therefore, the teachings of Yang are considered to meet the instant limitations to a compressed chewing gum tablet having a center comprising a compression of chewing gum granules.

38. Applicant argues (Remarks, pp. 9-10) that Yang does not teach a chewing gum tablet having a water content of less than 5% by weight.

39. It is unclear what Applicant is addressing when making this argument. Yang at claim 13 clearly teaches a gum base having a water content of 2-5%, which is further mixed with flavor oils, granulated, and compressed. These additional ingredients would not have been expected to increase the moisture content of the tablet above the

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claimed range. Yang further states that their invention is a "tabletted chewing gum containing 2% to 5% water (col. 2 lines 25-26). From these teachings, it would have been obvious to one of ordinary skill to provide a chewing gum tablet having less than 5% moisture.

40. Applicant argues (Remarks, p. 10) that the present invention does not rely on encapsulation of ingredients or compression aids.

41. In response, while the present invention may not rely on encapsulated ingredients, encapsulated ingredients are not excluded from the composition. Further, Applicant's specification at p. 16 lines 7-11 speaks to methods of encapsulating flavors which may be mixed into the gum base or compressed into the chewing gum.

42. Regarding the use of compression aids, as stated in the rejection, it would have been obvious to use the magnesium stearate in Yang as a lubricant in the outer layer of the tablets since the purpose of the magnesium stearate is to reduce friction between the inner die wall and the tablet edge during ejection and to prevent capping.

43. Applicant goes on to state that there is no teaching, suggestion or motivation by Yang to form a chewing gum tablet of the present invention (Remarks, p. 10).

44. As stated in the rejection, Yang teaches a compressed chewing gum comprising two different types of granules. There is no requirement that the ingredients not be encapsulated. Further, the instant invention allows for the use of compression aid compounds.

45. It is noted that the double patenting rejection over 11/028,684 was not addressed in the Remarks.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./

Nikki H. Dees
Examiner
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781